

REMARKS

This Amendment is responsive to the Final Office Action dated June 5, 2007. Applicant has amended claims 1, 25, 26 and 28, and added claim 30. Claims 1-17 and 24-30 are pending; of these, claims 13 and 14 are currently withdrawn.

Claim Rejection Under 35 U.S.C. § 112

The Final Office Action rejected claims 1-12, 15-17, 24-27 and 29 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant has amended claim 1 for purposes of clarification. Applicant submits that claims, as amended, recite subject matter clearly included in the present application as originally filed.

With respect to claims 1-12, 15-17, 24 and 25 Applicant amended independent claim 1 by substituting the term “majority” for the term “substantial portion”. Support for the amendment to claim 1 may be found from, e.g., FIG. 8 of the application as originally filed. In the context of the application as filed, FIG. 8 clearly depicts that a majority of IMD 12A is located within a pocket behind the scalp flap created by incision 18. Applicant has also amended paragraph [0036] to include a written description of this feature. The amendment to the specification is supported by FIG. 8.

With respect to claims 12 and 17, written description of the feature of placing an IMD within a recess is provided by, e.g., paragraph [0051] of Applicant’s specification as filed. The context of the application as filed provides support for the combination of placing an IMD within a pocket and a recess. For example, paragraph [0051] states in part, “In addition, the surgeon may in some cases determine that the skull of the patient may be prepared to receive the IMD.” (Emphasis added.)

With respect to claims 25, 26 and 29, written description of the feature of “placing all of” is provided by, e.g., paragraph [0022] of Applicant’s specification as filed, which states, in part, “[t]he pocket may be opened sufficiently to receive IMD 12 or a portion thereof.” This statement clearly illustrates that all or a portion of IMD 12 may be placed in a pocket. Applicant notes that mere rephrasing of a passage does not constitute new matter.¹

¹ *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973) as cited in MPEP 2163.07.

Each of the claims as currently pending clearly recited subject matter included in the present application as originally filed. For this reason, Applicant requests immediate withdrawal of each of the rejections under 35 U.S.C. 112.

Claim Rejection Under 35 U.S.C. § 102

The Final Office Action rejected claims 1-3, 5-10, 12, 15-17 and 25-27 under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,648,914 to Berrang et al. (hereinafter "Berrang"). The Final Office Action also rejected claims 1-4, 7, 15 and 25-27 under 35 U.S.C. 102(e) as being anticipated by U.S. Pub. No. 2003/0109903 Berrang et al. (hereinafter "Berrang Application"). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Claims 1-3, 5-10, 12, 15-17, 24 and 25

Applicant has amended claim 1 to recite placing a majority of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. Support for the amendment to claim 1 may be found from at least FIG. 8 of the application as originally filed. For example, FIG. 8 clearly depicts that a majority of IMD 12A is located within a pocket behind the scalp flap created by incision 18.

Berrang and Berrang Application fail to disclose a pocket adjacent to the fold and between the scalp and the skull, or placing a majority of a low-profile implantable medical device in the pocket as recited by claim 1. In fact, neither Berrang nor Berrang Application demonstrate that there is any separation whatsoever between a scalp and skull behind a fold as recited in claim 1. Applicant notes that neither Berrang nor Berrang Application discusses any such separation. For example, in contrast to claim 1 as amended, Berrang illustrates in FIG. 3 that at least a substantial majority of the implant is placed in front the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.² Berrang teaches raising the postauricular flap, and placing the device beneath the

² Berrang, column 13, lines 40-53.

flap, on the “flap” side of the fold. Berrang in no way suggests the additional step, after raising the flap, of creating a pocket adjacent to the fold and between the scalp and the skull. Because Berrang does not disclose creating a pocket, Berrang also does not disclose placing a majority of the low-profile implantable medical device in the pocket.

Similarly, Berrang Application also fails to teach or suggest such a feature. For example, as shown in FIG. 3 of Berrang Application, at least a substantial majority of the implant is placed in front the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.³

Because Berrang and Berrang Application fail to disclose a pocket, or placing a majority of a low-profile implantable medical device in the pocket as recited by claim 1, Berrang and Berrang Application each fail to anticipate the Applicant’s invention as recited in claim 1. For at least these reasons, the cited references fail to anticipate Applicant’s claims 1-3, 5-10, 12, 15-17, 24 and 25 as required to maintain the rejection under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

Claims 26 and 27

Independent claim 26 recites placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

In the rejection of claim 26, the Final Office Action states with reference to both Berrang and Berrang Application that “Figure 3 show (sic) an S-shaped incision and a pocket created right of the S-shaped incision, and adjacent a fold, in which all of the implant (as best understood by Applicant’s specification) is placed into.”⁴

However, as discussed with respect to claim 1, Berrang and Berrang Application each fail disclose placing a majority of a low-profile implantable medical device in the pocket. Applicant’s invention as recited by claim 26 further requires placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

³ Berrang Application, paragraph [0056].

⁴ Final Office Action, page 4.

In contrast to Applicant's invention as recited in claim 26, Berrang illustrates in FIG. 3 that at least a substantial majority of the implant is placed in front the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.⁵ Likewise, as shown in FIG. 3 of Berrang Application, at least a substantial majority of the implant is placed in front the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.⁶

In this manner, both Berrang and Berrang Application fail to anticipate Applicant's invention as recited by claim 26. For at least these reasons, the cited references fail to anticipate Applicant's claims 26 and 27 as required to maintain the rejection under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

The Final Office Action rejected claims 11, 24 and 28-29 as being unpatentable over Berrang or Berrang Application. Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claim 11

As discussed previously in this Amendment, Berrang and Berrang Application individually and collectively fail to disclose or suggest every element of independent claim 1. The rejection of claim 11 fails to overcome the deficiencies of Berrang and Berrang Application with respect to the elements of claim 1. For example, it would not have been obvious to one of ordinary skill in the art from the disclosures of Berrang and Berrang Application to separate a portion of the remainder of the scalp adjacent to the fold from the skull after separating the scalp flap from the skull to create a pocket adjacent to the fold and between the scalp and skull, and place a majority of a low-profile implantable medical device in such a pocket, as recited by independent claim 1. Because claim 11 is dependent on claim 1, the subject matter of claim 11

⁵ Berrang, column 13, lines 40-53.

⁶ Berrang Application, paragraph [0056].

would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention.

For at least these reasons, the Final Office Action fails to establish a prima facie case for non-patentability of Applicant's claim 11 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Claims 24 and 28-29

Independent claim 28 recites making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient. A similar feature is recited by claim 24, which is dependent on claim 1.

The Final Office Action acknowledges that such a feature is not disclosed by either Berrang or Berrang Application.⁷ The Final Office Action further states that even though Berrang and Berrang Application disclose that the preferably located behind the ear (as show in FIG. 3), that it would have been obvious to locate the device on top of the head to improve the aesthetics of the implanted device.⁸

Applicant respectfully disagrees with this reasoning. First, Berrang and Berrang Application disclose that the device is preferably located behind the ear. Additionally, Berrang and Berrang Application provide no suggestion that locating the device elsewhere may improve the aesthetics of the implanted device. Indeed, Applicant does not see how simply relocating the device on the skull of a patient would improve the aesthetics of the implanted device as the implanted device still result in a lump at the new location. Instead, Berrang discloses that in some embodiments, skull bone may be excavated.⁹ For this reason, if one of skill in the art sought to improve the aesthetics of the implanted device as suggested in the Final Office Action, one of skill in the art would not deviate from the preferred embodiment by relocating the device, but might instead excavate skull bone.

Furthermore, even if Berrang and Berrang Application did suggest relocating the implanted device, the references provide absolutely no suggestion that the device be relocated to the top of a head of a patient. In this manner, the Final Office Action appears to rely on

⁷ Final Office Action, page 5.

⁸ Final Office Action, page 5.

⁹ Berrang, column 10, lines 13-18.

Applicant's own disclosure as providing the motivation to locate an implanted device on the top of the head of the patient. This constitutes impermissible hindsight.

In addition, Berrang or Berrang Application teach away from the feature of making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient as recited by claim 21. Relocating components of the implanted devices described by Berrang and Berrang to the top of the head of the patient is impractical. For example, the implanted device disclosed by Berrang includes a microphone positioned adjacent an exterior auditory canal. The location of the microphone is integral to the operation of the implanted device.¹⁰ The implanted device disclosed by Berrang also includes an electrode array in one of the cochlea scala.¹¹ Relocating components of the device to the top of the head of a patient as suggested by the Final Office Action would increase the distance wires would need to be run to connect the components.

For at least these reasons, the Final Office Action fails to establish a prima facie case for non-patentability of Applicant's claims 24 and 28-29 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

New Claim

Applicant has added claim 30 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose a neurostimulator that provides deep brain stimulation, as recited by claim 30. Cochlear stimulation is not the same as or suggestive of deep brain stimulation

No new matter has been added by claim 30. For example, support for new claim 30 may be found from paragraph [0019] of Applicant's specification as filed.

¹⁰ See, e.g., Berrang, column 6, line 47 to column 7, line 10.

¹¹ See, e.g., Berrang, abstract.

CONCLUSION


All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce with any of the Examiner's current rejections or characterizations of the prior art, and reserve the right to further address such rejections and/or characterizations.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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By:

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